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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,673	10/02/2003	Hillary D. White	DC-0232	8827

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,673	WHITE, HILLARY D.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed February 27, 2006 have been entered.

Claims 1-9 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "testosterone derivative" and "growth hormone derivative" recite din the claims renders the claims indefinite because it is not clear what compounds may be considered as "testosterone derivative" and therefore, one of ordinary skill in the art would not be able to ascertain the metes and bounds of the claims.

The limitation "compounds that increases levels of growth hormone in blood" recited in claim 6 renders the claims indefinite because it is not clear what compounds may be considered as "compounds that increases levels of growth hormone in blood" and therefore, one of ordinary skill in the art would not be able to ascertain the metes and bounds of the claims.

The limitation "growth hormone releasing peptide mimetic compound" recited in claim 8 renders the claims indefinite because it is not clear what compounds may be considered as "growth hormone releasing peptide mimetic compound" and therefore,

one of ordinary skill in the art would not be able to ascertain the metes and bounds of the claims.

Response to Arguments

Applicant's arguments filed February 27, 2006 averring the instant specification defining the specific recited limitations have been fully considered but they are not persuasive. Examiner notes that although the specification does define what the recited limitation may be, the definition is an open-end definition. In other words, one of ordinary skill in the art would not have known what might be encompassed by the limitations recited in the claims. In addition, Applicant argues that one of ordinary skill in the art would recognize the term "testosterone derivative". Such arguments have been considered, but are not found persuasive. The metes and bounds of the compounds cannot be ascertained by the skilled artisan since it is not clear what compounds may be considered as "derivatives" of testosterone. The term "testosterone derivatives" means any compounds that are derived from testosterone. Without specific definition disclosed in the specification, one of ordinary skill in the art would not have known what compounds may be considered the derivatives of testosterone.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8, 10, and 13 of copending Application No. 10/464,310 ('310). Although the conflicting claims are not identical, they are not patentably distinct from each other because '310 recites the method of treating fibromyalgia by employing the very same agents of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's remarks on the outstanding double patenting rejection are acknowledged. Accordingly, the double patenting rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,935,949 ('949).

'949 teaches a method of treating fibromyalgia (muscle pain) by employing an androgen and DHEA, a testosterone derivative (See claims 1-5).

Response to Arguments

Applicant's arguments filed February 27, 2006 averring muscle pain as being ifferent from fibromyaglia have been fully considered but they are not persuasive. one of the symptoms patients with fibromyalgia experience is muscle pain. Therefore, the patent populations and symptoms treated taught in '949 are the same as those in the instant case. Accordingly, the claims are considered properly rejected under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,935,949 ('949) in view of US 5,656,606 ('606).

'949 teaches androgen, such as DHEA, as effective in treating fibromyalgia and chronic fatigue syndrome in peri/postmenstrual patients (See claims 1-5).

'949 does not expressly teach the incorporation of a secondary agent, such as growth hormone and hexarelin, in the method of treating fibromyalgia and chronic fatigue syndrome.

'606 teaches hexarelin and IGF-1 as well-known growth hormone secretagogues useful in treating fibromyalgia and chronic fatigue syndrome (See col. 23, line 42 and also claim 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate hexarelin and IGF-1 in the '949 method of treating fibromyalgia and chronic fatigue syndrome.

One of ordinary skill in the art would have been motivated to incorporate hexarelin and IGF-1 in the '949 method of treating fibromyalgia and chronic fatigue syndrome. Since hexarelin and IGF-1 are known to be useful in treating fibromyalgia and chronic fatigue syndrome, concomitantly employ the androgen and hexarelin or IGF-1 in a method of treating the very same diseases, i.e., fibromyalgia and chronic fatigue syndrome, would be considered obvious, absent evidence to the contrary (See *In re Kerkhoven* 205 USPQ 1069). At least an additive effect would be expected.

Response to Arguments

Applicant's arguments filed February 27, 2006 averring muscle pain as being different from fibromyalgia have been fully considered but they are not persuasive. Examiner notes that muscle pain (genus) is a general term, but fibromyalgia (specie) is a specific diseases that the symptoms is muscle pain. Therefore, the claims are considered properly rejected under 35 USC 103(a).

Applicant's arguments filed February 27, 2006 averring the cited prior arts' failure to hexarelin and IGF-1 alone to treat muscle pain have been considered, but are not found persuasive. Examiner notes that the claims recite the transitional phrase "comprising", which is an open-end transitional phrase. Therefore, any additional agents can be added in the recited method and nothing is excluded from the claims. Accordingly, the claims are properly rejected under 35 USC 103(a).

Applicant's arguments filed February 27, 2006 averring the cited prior arts' failure to provide motivation to combine have been considered, but are not found persuasive. The motivation to combine the teachings of the cited prior arts is based on the fact that the herein claimed agents as useful in treating fibromyalgia. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would concomitantly employ the herein claimed agents together in a single method of treating the very same disorder, fibromyalgia, absent evidence showing unexpected benefits (See *Kerkhoven* supra).

Applicant's arguments filed February 27, 2006 averring the administration of growth hormone would reduce the serum androgen level, based on Tapanainen et al. reference of record, and therefore unobvious for one of ordinary skill in the art to employ

both growth hormone and androgen together in a method of treating fibromyalgia have been considered, but are not found persuasive. According to Tapanainen et al., in the abstract and page 729, Figure 1, indicates that after the growth hormone administration, both the serum and FF testosterone level increase. Therefore, the arguments directed to the decrease of androgen level after growth hormone administration are not persuasive.

No unanswered arguments are seen to be present herein.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-

0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617